

of the at least one stent to the distal end thereof. As a result, a "sandwich" construction is formed in which a stent is positioned between two collagen covering layers that extend along and complements both the inside and outside surfaces of the stent frame. The sleeve is advantageously folded over at the proximal end and prevents blood flow between the two layers of collagen covering. When positioned in the vessel of a patient, the inside and outside collagen covering layers are in direct contact with the innermost surface of the vessel and allows for rapid remodeling and endothelialization of the stent graft covering. Since the inside and outside collagen covering is in, for the most part, direct contact with the vessel wall, the endothelialization or remodeling of endothelial cells is rapidly implemented. Thus, the diseased vessel wall or one having an aneurysm therein is rapidly repaired. Support can be found on page 5, lines 27-30 for the sleeve complementing the inside surface of the stent.

The Examiner has already indicated that the subject matter of dependent claim 10 is not anticipated by Buirge. Since the subject matter of dependent claim 10 has been amended and included in its entirety in independent claim 1, as amended herein, independent claim 1, as amended herein, and dependent claims 3 and 7-9 are not identically disclosed by Buirge, and it is thus requested that the rejection of these claims under 35 U.S.C. 102(b) as being anticipated by Buirge, be withdrawn.

With respect to the obviousness rejection of dependent claims 4-6 and 10, Douglas does not teach or suggest a covering initially twice the length of the at least one stent that extends along the inside and outside surfaces of the stent. In applicant's independent claim 1, as amended herein, the first portion of the sleeve extends along and complements an inside surface of the at least one stent. On the other hand, Douglas discloses and teaches the use of a bifurcated graft having a main body and two legs extending from the main body. A series of connected stents are longitudinally disposed about the lower end of each of the graft legs as depicted in Figs. 2, 4, 5 and 7e-7g of Douglas. Another series of connected stents 42 are longitudinally disposed around the upper end of both leg

grafts. The main body tubular member 32 is then positioned over the outer surface of connected stents 42. However, the Douglas reference does not disclose, teach or even suggest sandwiching the graft material on both the inside and outside surfaces of connected stents 42 as claimed in independent claim 1, as amended herein. Furthermore, independent claim 1, as amended herein, further requires that the collagen covering extend along and complement the inside surface of the stent. This is clearly not the case nor suggested in Douglas in which the two legs of the graft do not extend along and complement the inside surface of connected stents 42. As a result, the advantage of direct contact of the inside and outside layers of the collagen sleeve is lost in Douglas, since both the inside and outside layers are not in direct contact with the vessel wall to promote remodeling and endothelialization of the stent graft through the lumen thereof. Furthermore, Douglas does not even teach or suggest the use of collagen material for the purposes of remodeling. Rather, Douglas is directed to coating the sleeve with a collagen slurry for making the sleeve nonporous. The collagen slurry covering does not include any growth factors that would remodel host tissue as claimed in applicant's invention. In addition to not remodeling, the collagen slurry covering of Douglas addresses the problem of porosity and teaches in a direction opposite to that of Buirge as well as applicants' invention. Thus, there is no motivation for one skilled in the art to combine Buirge and Douglas, and a prima facie case of obviousness has not been established. Furthermore, a stent graft having a sleeve extending along and complementing the inside surface of a stent as well as its outside surface is not taught or suggested by the combination of Buirge and Douglas. In view thereof, applicants submit that independent claim 1, as amended herein, as including the amended subject matter of dependent claim 10 is not taught or suggested by Buirge and Douglas either singly or in combination, and it is requested that the rejection of independent claim 1, as amended herein, and dependent claims 4-6 under 35 U.S.C. 103(a) as being unpatentable over Buirge in view of Douglas, be withdrawn.

The reexamination and reconsideration of this application is respectfully requested, and it is further requested that the application be passed to issue.


Although the foregoing discussion is believed to be dispositive of the issues in this case, applicants' attorney requests a telephone interview with the Examiner to further discuss any unresolved issues remaining after the Examiner's consideration of this amendment.

Respectfully submitted,

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Date: Feb 12, 2003

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Enclosures:

Marked-Up Copy of Claims

Serial No. 09/849,044

PATENT  
Confirmation Copy

MARKED-UP COPY OF CLAIMS

1. (Twice Amended) A stent graft comprising:

at least one stent having a proximal end and a distal end and having a lumen extending therethrough between the proximal and distal ends, and

a covering of collagen having an extracellular matrix that becomes remodeled by host tissue, secured to the at least one stent and extending therealong between the proximal and distal ends, wherein the covering is a sleeve that initially has a length about equal to twice the length of the at least one stent, a first portion of the sleeve extends along and complements inside surface of the at least one stent, and a second portion of the sleeve is folded back over a proximal end of the at least one stent and then along an outside surface of the at least one stent to the distal end thereof.